UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

COLD SPRING HARBOR LABORATORY, Plaintiff

V.

ROPES & GRAY, LLP and MATTHEW VINCENT,

Defendants

11-CV-10128 -RGS

FIRST AMENDED COMPLAINT
JURY TRIAL DEMANDED

Plaintiff, Cold Spring Harbor Laboratory ("CSHL"), by its attorneys, hereby alleges as follows:

PARTIES

- CSHL is a New York education corporation chartered by the New York State
 Department of Education, with its principal place of business located in Cold Spring Harbor,
 New York.
- 2. Upon information and belief, defendant Ropes & Gray LLP ("R&G") is a Delaware limited liability partnership with its principal place of business in Boston, Massachusetts.
- 3. Defendant Matthew P. Vincent ("Vincent") was, until April 2009, a registered patent attorney and a partner in R&G's Intellectual Property group. Vincent received a Bachelors of Science degree in 1986 from Worcester Polytechnic Institute, a Ph.D. in Biochemical Sciences in 1991 from Tufts University School of Medicine, and a law degree in 1996 from Suffolk University Law School in Boston. Upon information and belief, Vincent is a resident of the State of Massachusetts.

4. As discussed in greater detail below, on or about July 20, 2009, Vincent filed his resignation from the practice of law with the Office of the Bar Counsel for the State of Massachusetts. Vincent's resignation resulted from an investigation into his misconduct that was the subject of a disciplinary investigation revolving around his having, for more than six years, under cover of a separate company which he formed, billed and collected from R&G's clients more than \$700,000 for work that could not be substantiated or verified, purportedly without R&G's knowledge that he owned said company. In late April 2009, R&G terminated Vincent's employment, purportedly because of the misconduct described above.

JURISDICTION AND VENUE

- 5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1338(a), 1367(a) and 1332(a).
- 6. Venue is appropriate in this judicial district pursuant to 28 U.S.C. § 1391(b)(1) in that R&G is subject to personal jurisdiction in this district and, thus, is a resident of this district, and pursuant to § 1391(b)(2) in that a substantial part of the events or omissions giving rise to CSHL's claims occurred in, and a substantial part of the property that is the subject of the action is situated in, this district.

SUMMARY OF CLAIMS

7. This case involves the negligence of R&G in prosecuting a series of patent applications on behalf of CSHL. These patent applications are directed to inventions made by Dr. Gregory Hannon, a Professor and Howard Hughes Medical Institute Investigator at CSHL, and his colleagues at CSHL (collectively, "Dr. Hannon"), which exploit a cellular mechanism called RNA interference ("RNAi"). Generally, RNAi refers to the process by which double stranded RNA functions to specifically silence expression of a cellular gene. Through his work

at CSHL, Dr. Hannon developed novel methods and technologies to specifically regulate the expression of target genes by using artificially created RNA molecules called short hairpin RNAs (shRNAs).

- 8. In its prosecution of patent applications intended to cover Dr. Hannon's shRNA inventions (the "Hannon Applications"), R&G, and in particular, Vincent, the R&G attorney responsible for prosecution of these patents, committed malpractice through their failure to conduct the prosecution according to a reasonable standard of care, with the result that their conduct has both delayed and prejudiced CSHL's efforts to obtain patent claims covering Dr. Hannon's inventions in several ways, as summarized below.
- 9. When Vincent drafted the three earliest non-provisional Hannon Applications (U.S. patent applications nos. 09/858,862, filed May 16, 2001, 09/866,557, filed March 24, 2001 and international patent application PCT/US01/08345, filed March 16, 2001), rather than providing an original, complete description of Dr. Hannon's work, Vincent instead relied upon copying extensive portions of text -- essentially verbatim -- from a prior patent application (WO/99/32619) published by a team led by another researcher in the RNAi field, Dr. Andrew Fire (collectively, "Fire"), to at least, in part, describe Dr. Hannon's inventions. About one half of the "Detailed Description of Certain Preferred Embodiments" found in the three earliest filed Hannon Applications consists of text copied from the Fire application. As described below, Vincent continued to rely upon this text to describe Dr. Hannon's inventions, and in particular, the shRNA technology that is the subject of the pending Hannon Applications. By relying extensively on the copied text, Vincent failed to fully describe and distinguish Dr. Hannon's inventions from the different technology invented by Fire.

- 10. During the course of prosecution, Vincent and R&G filed numerous follow-up continuation and continuation-in-part ("CIP") applications, allowing several opportunities to properly re-draft the Hannon Applications in such a way that relied on an original description of Dr. Hannon's own work to accurately describe the shRNA technology that Dr. Hannon invented. Instead, R&G and Vincent continued to rely upon the text copied from the Fire application, which falsely implied that Dr. Hannon's shRNA technology was either something that Fire invented or was suggested by the Fire application.
- 11. R&G and Vincent compounded the prejudice resulting from their continued use of the copied Fire text by failing to properly supplement the foregoing CIP applications with Dr. Hannon's ongoing work in a timely fashion. Furthermore, neither R&G nor Vincent ever brought the fact of this copying of the Fire text, and the potential prejudice resulting from that copying, to the attention of Dr. Hannon and CSHL. Despite being aware of how their negligent conduct had compromised the Hannon Applications, R&G and Vincent continued to prosecute the applications while hiding this fact from Dr. Hannon and CSHL. Vincent and R&G further compounded their negligence by their failure to properly attribute the copied text to Fire, effectively continuing to misrepresent that disclosure as being part of Dr. Hannon's work, and by years of delay in disclosing the Fire application to the United States Patent & Trademark Office (the "PTO"). Significantly, all this deprived Dr. Hannon and CSHL of any opportunity to mitigate the harm caused by Vincent and R&G's negligent prosecution, including the opportunity to appropriately re-draft the specification in a timely fashion to minimize any potential loss of priority.
- 12. It was the PTO that first noted the similarity of certain text in the Hannon Applications to that in the Fire application, a fact which ultimately brought R&G's and Vincent's

what the Fire application describes to warrant a patent.

STATEMENT OF FACTS

Background and Description of Relevant Technologies

- 13. CSHL is a private, not-for-profit research and education institution at the forefront of efforts in molecular biology and genetics to generate knowledge that will yield better diagnostics and treatments for cancer, neurological diseases and other major causes of human suffering.
- 14. Home to eight Nobelists, CSHL was founded in 1890 as one of the first institutions to specialize in genetics research and subsequently has played a central role in the seminal field of molecular biology. At CSHL in 1953, James D. Watson presented his first public lecture on his and Francis Crick's discovery of the double-helical structure of DNA, for which each later won a Nobel Prize. As Director and then President of the Laboratory from 1968 to 2003, Watson was instrumental in developing CSHL into one of the world's most influential cancer research centers.
- 15. Today, more than 400 scientists at CSHL pioneer the frontiers of biomedical research. A designated Center of the National Cancer Institute, CSHL has broken new ground in the study of cancer genetics. It has also taken a leading role in efforts to understand what causes neurodevelopmental and neurodegenerative illnesses such as autism, schizophrenia, and

Alzheimer's and Parkinson's diseases, and is a global leader in plant genetics and in the emerging discipline of quantitative biology.

- 16. Each year 8,000 of the world's leading life scientists are drawn to the campus for CSHL's legendary Meetings and Courses program, where new research is discussed and debated. The CSHL Press publishes textbooks and research journals that are among the most highly cited in their fields. CSHL also has created the DNA Learning Center, the nation's first science center dedicated to public genetics education. Its hands-on programs have reached 325,000 middle and high school students, teachers, and families since 1988, and its award-winning website millions more.
- 17. With regard to the Hannon Applications, of particular importance are the methods and technologies Dr. Hannon invented to use shRNAs in human and other mammalian cells. Since Dr. Hannon's invention, use of shRNA for gene silencing and regulation has become a valuable and widely adopted technology, which is used today in many different fields of medical and pharmaceutical research.
- 18. In 2002, Dr. Hannon's research on RNA interference was recognized by Science magazine as the Breakthrough of the Year and in 2005 by Esquire as a Breakthrough of the Decade. Recognized as one of the world's most accomplished scientists, Dr. Hannon has received numerous awards, including appointment as a Pew Scholar in the Biomedical Sciences and as a Rita Allen Foundation Scholar. In 2003, he received the U.S. Army Breast Cancer Research Program's Innovator Award; in 2005 the American Association for Cancer Research's Award for Outstanding Achievement in Cancer Research and in 2007 he received the National Academy of Sciences Award for Molecular Biology and The Memorial Sloan-Kettering Cancer Center's Paul Marks Prize for Cancer Research. He assumed his current position in 2005 as a

Howard Hughes Medical Institute Professor and continues to explore the mechanisms and regulation of RNA interference as well as its applications to cancer research.

- 19. CSHL is the assignee of the entire right, title, and interest in the Hannon Applications, which collectively refer to U.S. patent application numbers 09/858,862 filed May 16, 2001 ("the '862 application"), 09/866,557, filed March 24, 2001 ("the '557 application), 10/055,797 filed January 22, 2002 ("the '797 application"), 10/350,798 filed January 24, 2003, 10/997,086, filed November 23, 2004, 11/791,554 filed May 23, 2007, 11/894,676 filed August 20, 2007, 12/152,655 filed May 15, 2008, 12/152,837 filed May 16, 2008 and international patent applications PCT/US01/08435 filed March 16, 2001 ("the '435 PCT application"), PCT/US03/01963 filed January 22, 2003, and PCT/US05/42488 filed November 23, 2005, including all foreign patent applications filed therefrom. Certain of the Hannon Applications claim a benefit of priority to U.S. provisional applications 60/189,739 filed March 16, 2000 ("the '739 application"), and 60/243,097 filed October 24, 2000 ("the '097 application).
- 20. International Patent Application PCT/US98/27233, which was published on July 1, 1999 with International Publication Number WO/99/32619 (the "Fire application"), describes certain work conducted by Fire relating to his discovery that long double stranded RNA molecules could specifically silence gene expression in invertebrate cells. Fire referred generally to this cellular process as RNA interference, or RNAi.
- 21. Fire received U.S. Patent No. 6,506,559 for his RNAi technology, which issued on January 14, 2003 (the "Fire Patent"). The essentially identical written disclosures of the Fire application and the Fire Patent are referred to collectively hereinafter as the "Fire Specification."

Facts Relating to Malpractice

- 22. From in or around 2001 until late 2008, R&G acted as principal outside patent prosecution counsel for CSHL.
- 23. Vincent was the R&G attorney primarily involved in the drafting and prosecution of the all of the Hannon Applications, as well as the '739 application and the '097 application, to which certain of the Hannon Applications claim priority. To date, CSHL has paid R&G approximately \$420,000 in legal fees and disbursements that R&G has billed for its prosecution of the patent applications related to Dr. Hannon's shRNA technologies, and approximately \$1,400,000 in fees and disbursements that R&G has billed for its prosecution of other applications.
- 24. The '097 application includes about 11 pages of text that Vincent copied essentially verbatim, without citation or attribution, from the published Fire application.

 Attached as Exhibit A is a "marked-up" version of the '097 application, in which text that is the same as text in the Fire Specification is highlighted. Vincent specifically carried over at least some portion of the copied Fire text found in the '097 application into all of the subsequently filed Hannon Applications.
- 25. Despite the fact that Vincent was fully aware of the Fire application as early as October 2000, when he first copied text from that application into the '097 application, R&G did not cite the Fire application in any papers filed on behalf of CSHL until the Supplemental Information Disclosure Statement of November 26, 2004. And R&G did not cite the Fire Patent in any papers filed on behalf of CSHL until the Supplemental Information Disclosure Statement of January 7, 2005.

- 26. The '435 PCT application, filed March 16, 2001, the '862 application filed May 16, 2001, and the '557 application filed May 24, 2001 are directed generally to the initial methods and technologies Dr. Hannon developed relating to use of RNA interference in mammalian and other cells, including use of hairpin RNAs to regulate target genes. In particular, the filed '557 application included claims (20-25) directed to use of hairpin RNAs to inhibit gene expression and expression of such hairpin RNAs in cells of a transgenic non-human mammal.
- 27. About one half of the "Detailed Description of Certain Preferred Embodiments" (hereinafter, the "Detailed Description") found in the three earliest filed non-provisional Hannon Applications consists of text copied from the Fire application. Vincent's failure to provide an adequate description of Dr. Hannon's technology in these applications seriously compromised the ability of these applications, in particular the '557 application, to serve as priority support for Dr. Hannon's patent claims. This fact has deprived CSHL of the opportunity to obtain allowance of claims covering Dr. Hannon's inventions entitled to the respective filing dates of these applications, based on the support from these applications.
- 28. Vincent repeatedly effectuated this copying of Fire, notwithstanding that he knew from the outset that the Hannon Applications needed to be distinguished from Fire.
- 29. In this regard, the now pending claims of the Hannon '086 application are directed to one particularly valuable aspect of the technology Dr. Hannon developed, methods that allow one to stably suppress gene expression in mammalian cells using RNA interference. Among other things, this valuable technology provides an efficient, effective and widely applicable alternative to more expensive and laborious methods for biomedical research and drug development. Dr. Hannon's shRNA methods represented a considerable advance over the prior

art, including the Fire patent, which failed to provide any solution for how to use RNA interference in mammals, without killing the treated cells through the so-called "interferon" or "protein kinase (PK) response".

- 30. Vincent first added claims directed to use of hairpin RNAs to inhibit gene expression and expression of such hairpin RNAs in cells of a transgenic non-human mammal in the '557 application, which was filed May 24, 2001 as a continuation-in-part ("CIP") of the '435 PCT application. Both from the standpoint of meeting his duty of care and scientifically, in adding these new claims, Vincent had an affirmative duty to amend the specification with original text accurately describing these additional claimed inventions and distinguish these from the Fire application. However, instead of properly amending the Detailed Description, Vincent again relied on the same text he had previously copied from the Fire application as support for these new claims, knowing full well that text copied directly from Fire could not serve to distinguish the newly claimed subject matter from Fire.
- 31. During 2001, Vincent regularly communicated with Dr. Hannon regarding the Hannon Applications Vincent was then prosecuting. In filing the '557 application on May 24, 2001, and also in filing the '797 application in January 22, 2002, Vincent either knew or should have known the relevance and potential prejudice of continuing to rely on extensive passages of text copied from the Fire application. He should have told Dr. Hannon then what he had done. However, before filing the '557 application, and even the '797 application, Vincent failed to inform Dr. Hannon and CSHL (either directly or through Dr. Hannon) of this copying of Fire and Vincent's continued use of this copied text in the Detailed Description as support for the filed claims. His failure to do so deprived Dr. Hannon and CSHL of the timely opportunity to amend

the specification to properly describe and distinguish Dr. Hannon's technology from the different methods Fire described.

- 32. As corroborated by laboratory and other records, by the time Vincent had filed the '557 application, Dr. Hannon had already conceived of the short hairpin methods that are the subject of the now pending Hannon claims. Had Vincent in May 2001 informed CSHL and Dr. Hannon of his conduct, such information would have identified an urgent need to amend the '557 application to distinguish Dr. Hannon's hairpin technology, including in particular the use of short hairpins, from Fire's altogether different disclosure. Such amendment would necessarily have included adding original disclosure describing Dr. Hannon's short hairpin invention.
- 33. Vincent's failure to inform CSHL and Dr. Hannon of his conduct resulted in an entirely unnecessary and prejudicial delay in adding specific disclosure about the short hairpin invention to the Hannon Applications. To the extent Vincent eventually did so, this happened eight months later with the filing of the '797 CIP application on January 22, 2002. Even then, instead of revising the Detailed Description to provide an accurate description of the short hairpin technology, Vincent continued to improperly rely on the text he had copied from the Fire application, fully knowing that this text was directed to an entirely different invention. Had Vincent been forthright in May of 2001 about his copying of the Fire text, Vincent would have no doubt been apprised then (if he was not already aware) of Dr. Hannon's work relating to the short hairpin invention. Instead, by waiting until January 2002 to get reference to short hairpins into Dr. Hannon's applications, Vincent caused a potential crucial loss of priority from May 2001.
- 34. In short, even after the filing of the '557 application, Vincent and R&G failed to comply with a reasonable standard of care in the subsequent prosecution of these applications

and the filing of subsequent applications in the PTO based on these parent applications. Vincent and R&G never brought the fact of Vincent's copying of the Fire text, and the potential prejudice resulting from that copying, to the attention of CSHL. Despite being aware of how his conduct had compromised the Hannon Applications, Vincent continued to prosecute them while hiding this fact from CSHL. Significantly, this deprived CSHL of any opportunity to address the issues the copying raised early in prosecution, when the applications could have been re-drafted in a timely fashion to minimize any potential loss of priority and minimize the harm to CSHL.

- 35. Further compounding the harm Vincent had caused, in prosecuting these early applications, Vincent's and R&G's improperly relied on and misrepresented the copied Fire text as describing the technology Dr. Hannon invented. In effect, their actions erroneously implied that Dr. Hannon's technology was previously invented or described by Fire, which it was not. Through their failure to properly attribute the copied text to Fire, and years of delay in even bringing the Fire application and Fire Patent to the attention of the PTO, Vincent and R&G further compounded their malpractice by effectively continuing to misrepresent that disclosure as being part of Dr. Hannon's work.
- 36. For example, these misrepresentations include statements made during prosecution of the '557 application. In the office action dated April 21, 2005 rejecting all pending claims, the PTO Examiner argued that the specification failed to teach introducing an expression vector encoding a hairpin RNA into mammalian cells. In response (Reply and Amendment filed August 11, 2005), R&G argued that the application described the use of expression systems that are intended to produce hairpin RNAs upon being transcribed in cells. In support, R&G repeatedly pointed to various sections of text copied from the Fire application. To support its position, R&G filed a Rule 132 Expert Declaration (Declaration under 35 U.S.C.

- §1.132 of Frank McKeon dated July 29, 2005), which cited repeatedly to sections of the copied Fire text as evidence that the technology invented by Dr. Hannon and described in the '557 application was directed to use of expression systems intended to produce hairpin RNAs upon being transcribed in cells.
- 37. As stated above, instead of properly re-drafting the Hannon Applications via the numerous CIP applications, in a way that relied upon an original description of Dr. Hannon's work, Vincent and R&G continued to rely on text copied from Fire despite the fact that this risked the false implication that Dr. Hannon's shRNA technology was either something that Fire invented or was suggested by the Fire application.
- 38. Notably, on August 11, 2005, the PTO issued a Notice of Allowance for the pending '557 application claims. In explaining his reasons for allowance, the Examiner stated on page 3:

The declarations under 37 CFR 1.132 filed August 11, 2005 are sufficient to overcome the rejections of claims...based upon new matter under 35 USC 112 first paragraph and lack of enablement under 35 USC 112 first paragraph.

Specifically, the declaration of Frank Mckeon establishes that the double stranded RNA construct of the patent application encompass hairpin RNA comprising the features claimed therein. The declaration provides evidence by specific examples in the instant application.

39. On April 6, 2006, however, the PTO withdrew the '557 application from issue to reconsider its decision. On September 6, 2006, the Examiner rejected all pending claims as anticipated by the Fire Patent.

- 40. The prejudice to the Hannon Applications caused by Vincent's original attempt to describe the Hannon inventions by copying text from Fire application was illustrated by R&G's subsequent failed efforts to overcome the Fire Patent as prior art against the '557 application. In the Amendment filed March 9, 2007, Vincent argued that in contrast to the disclosure of the '557 application, the Fire Patent failed to provide any particular guidance that would have led one to envisage the claimed methods directed to using an expression vector encoding a hairpin RNA to attenuate gene expression specifically in mammalian cells.
- 41. In fact, before filing the March 9, 2007 Amendment, Vincent conducted an inperson interview in February with Examiner McGarry and Supervisory Examiner Schultz at the PTO, specifically to discuss the Examiner McGarry's rejection of the pending claims as anticipated by the Fire Patent. Notably, Vincent brought with him to the interview both Dr. Hannon and John Maroney, the Vice President, Legal Counsel, and Director of CSHL's Office of Technology Transfer. During this interview, Vincent provided the Examiners with a preview of the argument he planned to present in the March 9, 2007 Amendment. Despite the fact that his planned arguments relied on text copied from the Fire specification, Vincent never disclosed this fact to Examiners McGarry and Schultz, Dr. Hannon or Mr. Maroney.
- 42. In the Office Action dated September 4, 2007, the PTO rejected Vincent's argument that only the '557 specification provided such guidance. Referring specifically to the text that Vincent had copied from Fire, the PTO noted that "in fact the disclosure of cell/organisms of the instant specification at pages 21-22 is essentially verbatim of the disclosure of Fire et al at column 8," and that "it is unclear how applicant claimed invention differs from what has been disclosed by the prior art."

- 43. The '797 application was filed as a continuation-in-part of the '435 PCT application and among other things, incorporated additional disclosures from Dr. Hannon relating to the use of the shRNA technology for regulating gene expression in mammalian cells. This added material was directed to an entirely different invention from the technology described in the Fire application. Despite that fact, Vincent retained the copied Fire text in the Detailed Description, fully knowing that the copied Fire text described a different invention.
- 44. In copying Fire again in filing the '797 application, Vincent furthered his malpractice by again failing to make any reasonable effort to amend the specification, in either the summary or detailed description of the invention, to accurately support claims directed to use of short hairpins in mammalian cells. Instead, Vincent continued to rely on the extensively copied Fire text as support. The prejudicial consequence of Vincent's actions has been repeatedly demonstrated in attempts to draft claims specifically defining "short hairpins" in a manner that unambiguously distinguishes "short hairpins" from the "long hairpins" that the PTO (albeit improperly) now alleges are described by Fire.
- 45. In this regard, during prosecution of the '557 application, the examiner rejected Vincent's attempt to add a numerical limitation to the hairpin claims, noting that the attempt to add a specific numeric upper limit to such claims "is not consistent with the specification and constitutes new matter where it is not disclosed nor made apparent by the disclosure of the specification that such a specific range was intended."
- 46. With respect to the short hairpin claims now pending in the '086 and '676 applications, Vincent's failure to properly supplement the '797 application with original disclosure specifically describing the short hairpin invention compounded the problem Vincent created by improperly relying on the copied Fire text. The continued harm these actions has

caused is evident from the examiner's pending rejection of short hairpin claims in the '086 and '676 applications (filed from and claiming priority to the '797 application) as being anticipated by Fire.

- 47. Vincent's failure to properly distinguish Dr. Hannon's invention was further compounded by his failure to include additional disclosure regarding use of shRNA in mammalian cells that Dr. Hannon had available at the time that he filed the '797 application. This material, among other things, included data and other information Dr. Hannon provided in the article published as Genes & Development 16:948-958, a draft of which Dr. Hannon first sent to the journal on or about the '797 filing date.
- 48. In short, as a direct result of Vincent's and R&G's malpractice, the Hannon Applications have been unfairly prejudiced and compromised by the erroneous perception that the technology invented by Dr. Hannon is not sufficiently unique from what the Fire application describes to warrant a patent. Such a perception, created by Vincent's and R&G's misconduct, directly contributed to R&G's failure to obtain any allowed claims covering Dr. Hannon's invention.
- 49. Before, and increasingly throughout 2007, Mr. Maroney experienced frustration with a lack of communication from Vincent about the Hannon Applications, and in particular about Vincent's understanding of why the PTO had withdrawn the '557 application from issue.
- 50. Dr. Vladimir Drozdoff is a Senior Licensing Associate and Patent Attorney for CSHL's Office of Technology Transfer. Dr. Drozdoff first began working at CSHL on February 11, 2008, with one of his first priorities being a review of Vincent's prosecution of the Hannon Applications.

- 51. Dr. Drozdoff first became aware of apparent copying of text from the Fire Specifications into the Hannon Applications upon reviewing the Office Action of September 4, 2007. In that Office Action, the Examiner noted the similarity of certain text to that in the Fire specification, in particular on both page 8 and page 10, that "the disclosure of cell[s]/organisms of the instant specification at pages 21-22 is essentially verbatim of the disclosure of Fire et al. at column 8."
- 52. Dr. Drozdoff then compared the entire '557 specification with the entire Fire Patent, observing that the similarity extended beyond column 8 of the Fire Patent. Consequently, he conducted a further review of the Hannon Applications, which included a detailed comparison of the '739 application and the '097 application, to which the Hannon Applications claim priority, to the text of the Fire Patent and the published Fire application.
- 53. As a result of Dr. Drozdoff's investigation, the following facts were evident: (1) The "Summary of the Invention" of the '097 application contains approximately 11 pages of text that is almost identical to text found in the Fire application and in the Fire Patent; (2) this text is found in the Fire application in certain portions of 3 pages within the "Summary of Invention" and in certain portions of 13 pages within the "Detailed Description of the Invention"; (3) a substantial portion of this text was carried forward into the specification of the various Hannon Applications; (4) none of the sections of the Hannon Applications where this text appears cite or reference the Fire application; and (5) the Fire application was first disclosed in the '557 prosecution in a November, 2004 filed IDS.
- 54. Mr. Maroney first became aware of apparent copying of text from the Fire Specifications into the Hannon Applications upon being advised of the same by Dr. Drozdoff on March 3, 2008. Before Dr. Drozdoff provided Mr. Maroney with this information on March 3,

2008, it had been his belief that the text of the '097 priority application and of the various Hannon Applications consisted of text drafted by Vincent along with text generated by the inventors, such as portions of draft manuscripts. This was the first time Mr. Maroney, or, to the best of his knowledge, anyone at CSHL, had been informed or had become aware that either the '097 priority application or any of the Hannon Applications contained numerous pages of text almost identical to text appearing in the Fire application.

- 55. Dr. Hannon first became aware of apparent copying of text from the Fire Specifications into the Hannon Applications upon being advised of the same by Dr. Drozdoff and Mr. Maroney on March 18, 2008.
- 56. To the extent that any papers were filed with the PTO, or any statements were made to the PTO, during the prosecution of the Hannon Applications, including any statements made to the PTO about the Fire Patent or the Fire application or any statements made about the Hannon Applications that involved sections that are the same as sections of the Fire Specifications, all such statements were made without any knowledge on the part of Dr. Drozdoff, Mr. Maroney, or Dr. Hannon, or, to the best of their knowledge, on the part of CSHL, that the specifications of the Hannon Applications contain text that is the same as, or very similar to, text from the Fire Specifications.
- 57. Upon being made aware of the above facts, in accordance with CSHL's duty of candor and good faith in dealing with the PTO, and with CSHL's desire to maintain the highest levels of scientific integrity, Dr. Drozdoff and Mr. Maroney, acting on behalf of CSHL, took steps to further investigate and diligently rectify any impropriety that may have occurred in the prosecution of the Hannon Applications, as a result of the facts described above. These steps included meeting with Vincent and R&G partner James Haley to inform them of CSHL's

findings, requesting R&G's full cooperation to provide the PTO with complete disclosure of these facts and in carrying out an entire, orderly transfer of responsibility for prosecution of the Hannon Applications from Vincent.

- 58. Accordingly, to understand what Vincent knew, Dr. Drozdoff and Mr. Maroney arranged to meet in New York City with Vincent and James Haley, a partner and patent attorney at R&G. During this meeting, which was held on April 1, 2008, Dr. Drozdoff and Mr. Maroney informed them of Dr. Drozdoff's findings regarding the similarity of certain text in the Hannon Applications and the Fire application and Fire Patent, and provided Vincent and Mr. Haley with a comparison of the '097 application to the Fire Specifications. Vincent acknowledged that in filing the '097 application, he was aware that portions thereof had been copied from the published Fire Specifications. At no time during this meeting did Vincent indicate that he had ever informed the PTO, CSHL or any of the co-inventors of this fact.
- 59. R&G refused to assure CSHL that it would unconditionally assist CSHL in providing the PTO with all relevant facts, instead imposing on CSHL the precondition that required CSHL to first sign a waiver essentially releasing R&G from any liability for misconduct. So that CSHL could carry out its first priority to provide the PTO with full disclosure, CSHL engaged Wilmer Cutler Pickering Hale and Dorr, LLP as new counsel.
- 60. As a result of their malpractice, R&G and Vincent failed to obtain allowance of any of the Hannon Applications and have caused CSHL to incur substantial, unnecessary and avoidable costs for their prosecution. Not only has CSHL been damaged in the form of hundreds of thousands of dollars in legal fees paid to R&G that would not have been necessary had Vincent and R&G met their duties of care, but CSHL, having been denied patents that it

otherwise would have received but for R&G's and Vincent's negligence, has lost millions of dollars in potential licensing fees for the Hannon Applications.

Facts Related to Conflict of Interest

- 61. Upon information and belief, sometime prior to November 4, 2002, Insert Therapeutics, Inc. ("Insert") retained Vincent and R&G as its prosecution counsel. Prior to Vincent's representation, Insert's technology related to cylcoldextrin-containing inclusion complexes for use as drug delivery systems. Upon information and belief, Insert had no expertise in the field of RNAi. Insert's founder was Marc Davis, a professor of chemical engineering at California Technical Institute.
- 62. On November 4, 2002, Vincent filed U.S. application no. 10/288,230 ("230 application") on behalf of Insert entitled "METHODS AND COMPOSITIONS FOR THERAPEUTIC USE OF RNA INTERFERENCE." Upon information and belief, Vincent coopted the inventions of CSHL for the benefit of Insert by including them in the invention disclosure of the '230 application, including the disclosure of a "hairpin" RNA of "19-30 base pairs in length."
- 63. In and around June, 2004, Vincent approached Dr. Hannon to propose that CSHL and Insert combine patent portfolios and expertise in a new venture. Vincent never presented the venture proposal to CSHL attorneys or management. Nor did he disclose that he had filed a patent application on Insert's behalf containing CSHL inventions.
- 64. Upon information and belief, R&G conducted a conflict avoidance investigation in connection with representation of Insert in patent prosecution matters. Upon information and belief, the representation cleared conflict.

- 65. On June 4, 2004, Insert was acquired by Arrowhead Research Corporation ("Arrowhead"). At that time, Arrowhead described itself as "engaged in continuing efforts to finance research in various aspects in the 'nano-technology' field, with a view toward realizing future revenue and profit from any such technologies that might result from the Company sponsored research."
- 66. On February 22, 2005, Arrowhead, Davis, and Vincent co-founded Calando Pharmaceuticals, Inc. ("Calando I"), the purpose of which was to develop and commercialize technologies for the therapeutic use of RNAi, including the technology developed at CSHL's laboratories and obtained by Vincent in connection with his representation of CSHL, and to exploit the purported intellectual property of Insert, including the subject matter of the '230 application. Shortly after the formation of Calando I, Insert and Calando I entered into a license agreement giving Calando I exclusive rights to Insert's technology for the delivery and therapeutic use of RNAi in Calando I's research, development and business efforts.
- 67. In and around January 2008, Arrowhead, Davis and Vincent effectuated a merger between Calando I and Insert. Upon information and belief, as part of the merger, Vincent's stock in Calando I was exchanged for stock in the merged company, which retained the name Calando Pharmaceutical, Inc. ("Calando II"). As part of the merger, Calando II acquired all rights, title and interest in Insert intellectual property, including applications drawing priority to the '230 application.
- 68. Vincent never disclosed his ownership interest in Calando I to CSHL attorneys or management. Nor did he disclose his ownership interest in Calando II. Upon information and belief, R&G was aware of Vincent's ownership in Calando I and Calando II but failed to disclose that information to CSHL. R&G continues to prosecute applications originally filed by Insert

and now assigned to Calando II, including applications claiming technology developed at CSHL's laboratories and obtained by Vincent in connection with his representation of CSHL including applications claiming priority to the '230 application.

- 69. In April 2006, Vincent approached Dr. Hannon to propose that CSHL and Calando I form a new venture for the development and commercialization of short hairpin RNAi. Vincent never disclosed that he had an ownership interest in Calando I nor presented the venture proposal to CSHL attorneys or management. Vincent also never disclosed that Calando I was the exclusive licensee of Insert's purported intellectual property, including applications claiming priority to the 230 application.
- 70. Upon information and belief, Vincent was aware of CSHL shRNA know- how and trade secret information and shared such information in connection with his relationship with Insert and Calando.
- 71. In March 2007, CSHL and RXi Pharmaceuticals Corporation ("RXi") entered into a license agreement for CSHL's shRNA technology. Beginning as late as February 2007, however, R&G had been engaged by RXi without CSHL's knowledge or consent.
- 72. On October 11, 2007, Vincent emailed John Maroney requesting waiver of conflict for Marc Rubenstein, a partner at R&G, to represent RXi as corporate counsel. Vincent, however, never notified CSHL that R&G had already been retained by RXi. Moreover, Vincent never disclosed to CSHL that he was asked to represent RXi in connection with prosecution of RXi patent applications; nor did he request a waiver of conflict in connection with such representation. Vincent was retained by RXi to prosecute its patent applications in 2008 and R&G continues to act as RXi's counsel.

73. Upon information and belief, R&G conducted a conflict avoidance investigation in connection with representation of RXi. Upon information and belief, based on the investigation, R&G identified a conflict but failed to seek a waiver from CSHL until after R&G had already been engaged. Upon information and belief, R&G never sought a waiver in connection with representation of RXi as patent counsel.

Vincent's Termination by R&G and Subsequent

Resignation from the Practice of Law

- 74. In late April 2009, R&G abruptly terminated Vincent's employment.
- 75. The purported basis for this termination is conduct by Vincent that was the subject of a pending State of Massachusetts disciplinary proceeding at the time of Vincent's termination, as described below.
- 76. On or about July 20, 2009, Vincent tendered his voluntary resignation from the practice of law, as a result of said investigation. Vincent's own affidavit in support thereof acknowledged the truth of the material facts upon which the disciplinary charges were based, including the following:
 - a. At some time prior to April 2002, Vincent formed a business entity known as
 "The IP Resource Company" to perform patent database searches;
 - b. Vincent did not inform his partners at R&G or his clients that he was the owner and operator of The IP Resource Company;
 - c. Beginning in approximately April 2002 and continuing through approximately September, 2008, Vincent prepared and submitted to R&G for payment sixty separate invoices from The IP Resource Company, each invoice relating to multiple patent matters;

- d. The invoices that Vincent prepared stated, in summary form, that The IP Resource Company had performed research tasks on a total of approximately 3449 separate client matters and was entitled to payment of a total of \$733,771.30 for those services. The invoices did not itemize costs, services rendered, dates on which services were rendered, or time spent.
- e. Vincent approved each of the sixty invoices for payment and forwarded them to R&G's accounting department.
- f. Relying on Vincent's approval, R&G paid the invoices and billed the appropriate clients for the service.
- g. Vincent endorsed the checks for deposit and caused them to be deposited in an account for his personal use.
- h. Vincent either never maintained or did not retain the underlying billing records for the invoices submitted by the IP Resource Company, and he cannot satisfactorily account for costs incurred and services rendered.
- 77. CSHL was among the clients of R&G who were victimized by Vincent's conduct described above. While serving as CSHL's primary patent prosecution counsel, R&G billed and collected approximately \$10,000 from CSHL in the name of work allegedly performed by IP Resource Company at the request, and/or with the approval, of R&G.
- 78. Upon information and belief, during the time Vincent was employed at R&G and acted as counsel for CSHL, R&G had notice that Vincent's conduct as an attorney in connection with his representation of CSHL as well as other R&G clients may have or did in fact fall substantially below applicable professional standards for representing an entity in CSHL's position in pursuing patents such as the Hannon Applications, and may have or did in fact fail to

conform to New York, Massachusetts and/or PTO rules of ethics. In this regard, R&G also failed to properly manage and supervise Vincent, his work, the and also failed to properly investigate Vincent's outside business interests, including his ownership interests in Arrowhead and Insert.

79. Upon information and belief, R&G failed to notify CSHL of such facts and allow CSHL a fair opportunity to evaluate whether retaining Vincent as its counsel was in it best interests. Such failure to timely notify CSHL deprived CSHL of a fair opportunity to select alternative counsel on matters in which Vincent represented CSHL or was otherwise responsible for legal work done on behalf of CSHL.

FIRST CLAIM

(Legal Malpractice)

- 80. CSHL repeats and realleges the allegations made in paragraphs 1 through 56 and 60 above.
- 81. Vincent and R&G acted as attorneys for CSHL from in or around 2001 through September 2008. During this time frame, Vincent and R&G owed CSHL a duty of care.
- 82. During this time frame, Vincent and R&G were the only attorneys acting on behalf of CSHL in the patent prosecution of the Hannon Applications.
- 83. In taking the actions, and omitting to act, as described in Paragraphs 22-56 above, Mr. Vincent's and R&G's actions were negligent and fell below the applicable professional standards for representing an entity in CSHL's position in pursuing patents such as the Hannon Applications.
- 84. But for Vincent's and R&G's failures to satisfy their duties of care to CSHL, it would have been able to obtain allowance of claims covering Dr. Hannon's inventions.

- 85. As a direct and proximate result of Vincent's and R&G's negligence, CSHL has been severely damaged. CSHL has spent hundreds of thousands of dollars on legal fees that would not have been necessary had Vincent and R&G met their duties of care. These fees include substantial additional costs that CSHL has incurred resulting from its transfer of prosecution to new counsel and in legal work that new counsel has conducted in an attempt to address the harm caused by R&G's misconduct to the Hannon Applications, as well as fees paid to R&G that would not have been necessary had Vincent and R&G satisfied their duties of care. CSHL will establish the exact amount of this category of damages at trial, but expects it to be no less than \$1,000,000.
- 86. In addition, CSHL has lost opportunities for licensing Dr. Hannon's technology, including at minimum, lost opportunities resulting from the loss of patent term caused directly by Vincent's and R&G's malpractice. The resulting losses include lost opportunities for commercial user licenses, allowing commercial use of shRNA technology, as well as lost royalty income on research reagent sales. The exact amount of such damages will be established at trial. However, CSHL expects that the annual amount of such licensing opportunities it has lost as a direct and proximate result of Vincent's and R&G's malpractice to be at least \$22,500,000 for lost commercial user license income and \$9,000,000 for lost royalty income, should CSHL ultimately obtain the patent such that only five years of patent term are lost, to \$57,500,000 for lost commercial user license income and \$19,000,000 for lost royalty income, should CSHL be denied the patent such that fifteen years of patent term are lost.
- 87. In addition, as a direct and proximate result of their negligence, Vincent's and R&G's failure to obtain issuance of claims to CSHL's shRNA technology has precluded CSHL from pursuing opportunities to further commercialize this technology through a start-up

company. The exact amount of such damages will be established at trial. However, CSHL expects that the start-up income it has lost as a direct and proximate result of Vincent's and R&G's malpractice to be at least \$5,000,000. In sum total, depending on the number of years of term lost, CSHL expects its total damages as a direct and proximate result of Vincent's and R&G's malpractice to be at least \$37,500,000 to \$82,500,000.

SECOND CLAIM

(Breach of Fiduciary Duty)

- 88. CSHL repeats and realleges the allegations made in paragraphs 1 78 above.
- 89. As attorneys for CSHL, R&G and Vincent owed CSHL a fiduciary duty of competence.
- 90. R&G and Vincent also owed CSHL a fiduciary duty of loyalty, including a duty to exercise judgment solely for the benefit of CSHL and free of compromising influences and loyalties arising from Vincent's responsibilities for other clients and from his own interests. In connection with his duty of loyalty, R&G and Vincent also had a duty to communicate with CSHL to obtain its informed consent, confirmed in writing, to resolve any conflict.
- 91. In taking the actions, and omitting to act, as described in Paragraphs 22-60 and 74-78 above, Mr. Vincent's and R&G's actions were in breach of their fiduciary duties of competence to CSHL.
- 92. In taking the actions, and omitting to act, as described in Paragraphs 61-73 above, Mr. Vincent's and R&G's actions were in breach of their fiduciary duties of loyalty to CSHL.
- 93. In particular, Vincent breached his duty of loyalty to CSHL Vincent when he coopted the inventions of CSHL for the benefit of his other client, Insert, by including CSHLderived subject matter in the invention disclosure of the '230 application, including subject

matter relating to a "hairpin" RNA of "19-30 base pairs in length" and continuing to represent Insert in the prosecution of applications containing CSHL-derived subject matter. Vincent further breached his duty by failing to inform CSHL of the nature of the representation of Insert and the CSHL-derived subject matter contained in Insert applications, both at the time Vincent was preparing the '230 application and later when Vincent approached Dr. Hannon to propose that CSHL and Insert combine patent portfolios and expertise in a new venture. By failing to properly inform CSHL, Vincent never obtained CSHL's informed consent to Vincent's representation of Insert in its prosecution and business dealings. Moreover, Vincent prevented CSHL from making an informed decision of whether to do business with Insert. R&G breached its fiduciary duty by permitting Vincent to represent Insert.

- 94. Vincent breached his duty of loyalty to CSHL by co-founding and participating in the business of Calando I. Vincent further breached his duty by failing to inform CSHL of his ownership interest in Calando I and Calando I's exclusive license to Insert's purported intellectual property, including the '230 application and other applications containing CSHL-derived subject matter, both at the time of the formation of Calando I and later when Vincent approached Dr. Hannon to propose that CSHL and Calando I form a new venture for the development and commercialization of short hairpin RNAi. By failing to properly inform CSHL, Vincent never obtained informed consent from CSHL to Vincent's ownership in Calando I and participation in its business. Moreover, Vincent prevented CSHL from making an informed decision of whether to do business with Calando I. R&G breached its fiduciary duty by permitting Vincent to own and participate in the business of Calando I.
- 95. Vincent breached his duty of loyalty to CSHL by obtaining equity interest in Calando II, which upon merger with Insert, became owner in all rights title and interest in

Insert's purported intellectual property. Vincent further breached his duty by failing to inform CSHL of his ownership interest in Calando II. By failing to properly inform CSHL, Vincent never obtained informed consent from CSHL to Vincent's ownership in Calando II. R&G breached its fiduciary duty by permitting Vincent to own and participate in the business of Calando II.

- 96. R&G and Vincent breached their duties of loyalty to CSHL by representing RXi in patent prosecution and corporate matters without informed consent.
- 97. In taking the actions, and omitting to act, as described in Paragraphs 1-79 above, Vincent's and R&G's actions were in breach of their fiduciary duties to CSHL.
- 98. Had Vincent and R&G satisfied their duties of care to CSHL, CSHL would have prevented or, at a minimum, ameliorated, the harm caused by the negligent and fraudulent acts as set forth in paragraphs 1-87 above and CSHL would have had information to make an informed decision to seek substitute counsel.
- 99. Had Vincent and R&G satisfied their duties of care, Insert and Calando would have come to CSHL to obtain a license to the Hannon technology.
- 100. As a direct and proximate result of Vincent's and R&G's breach of fiduciary duties, CSHL has suffered damages in an amount to be determined at trial.
- 101. Specifically, CSHL has been damaged in the form of: (i) additional attorneys' fees that it has been forced to expend as a result of R&G's and Vincent's wrongful acts and omissions, which is estimated to be no less than \$500,000; (ii) lost licensing opportunities for the Hannon technology, which is estimated to be worth no less than \$36,500,000 to \$81,500,000; and (iii) disgorgement of all attorneys' fees paid by CSHL to R&G since 2001, which is estimated to be no less than \$1,400,000.

THIRD CLAIM

(Fraud and Fraudulent Concealment)

- 102. CSHL repeats and realleges the allegations made in paragraphs 1 through 79 above.
- 103. For more than eight years, while acting as primary patent prosecution counsel for CSHL, by intentionally and repeatedly concealing Vincent's copying of Fire, Vincent and R&G committed a fraud upon CSHL.
- 104. Vincent and R&G failed to inform CSHL of the copying of Fire, and failed to inform the PTO of the copying of Fire, despite their professional obligation to make such disclosure. This withholding of material information was intentionally done by Vincent and R&G for the purpose of, and had the effect of, inducing CSHL to continue using Vincent and R&G as its primary patent counsel, and to reasonably rely on their advice in the mistaken belief that they had undertaken to provide professional advice in CSHL's best interests and had done nothing to stain CSHL's reputation or credibility with the PTO, or prejudice its patent applications.
- 105. On this point, shortly before filing the March 9, 2007 Amendment in the '557 application, Vincent went with Dr. Hannon and Mr. Maroney to meet with the examiner, essentially over the examiner's pending rejection of claims as being anticipated by Fire.

 Incredibly, Vincent still never brought to their attention the copying and resulting problems that he created in distinguishing Dr. Hannon's work from Fire.
- 106. Had Vincent been forthright about his copying of Fire anytime during the course of the prosecution of the Hannon Applications, CSHL would never have kept Vincent and R&G as its patent counsel. By intentionally concealing what actually had transpired, Vincent and

R&G intentionally induced CSHL to continue using Vincent and R&G for a majority of its patent work.

- 107. Vincent and R&G, as attorneys for CSHL, had a duty to disclose their copying of Fire and the prejudice to the Hannon Applications that their continued reliance on the copied text had caused, as described above, which was material information.
- 108. As a result of this fraudulent concealment and CSHL's reasonable reliance on the deceptive statements made by Vincent and R&G (via the filed Hannon Applications) that failed to disclose the copying of Fire, CSHL has been damaged in an amount to be determined at trial, including punitive damages.
- 109. Vincent committed a separate fraud upon CSHL through his tendering, through R&G, of invoices from The IP Resource Company totaling at least \$9587.45, all of which were paid by CSHL, notwithstanding that, upon information and belief, Vincent could not substantiate any work performed by that company for the benefit of CSHL. The statements of work performed set forth on these invoices constituted material misrepresentations.
- 110. Vincent tendered these invoices to CSHL, through R&G, knowing that they were false, with the intent that CSHL would rely on the statements contained in those invoices, and the fact that they were being tendered to CSHL by R&G, in making payment thereon.
- 111. CSHL reasonably relied on the statements of work performed contained in the invoices of The IP Resource Company invoices forwarded for payment by R&G.
- 112. In making payment on these fraudulent invoices, CSHL suffered damages in an amount to be determined at trial, plus punitive damages.

FOURTH CLAIM

(Negligence)

- 113. CSHL repeats and realleges the allegations made in paragraphs 1 through 79 above.
- 114. R&G owed CSHL a duty of care, including a duty to ensure that the work of Vincent was adequately supervised, a duty to ensure that Vincent's work met applicable professional standards for representing an entity in CSHL's position in pursuing patents such as the Hannon Applications and a duty to make reasonable efforts to ensure that Vincent conformed to applicable rules of ethics.
- 115. During Vincent's employment with R&G, R&G failed to properly manage and supervise Vincent, his work, and the conduct of this practice. R&G also failed to properly investigate Vincent's outside business interests, including his ownership interests in Calando I and Calando II.
- 116. R&G further failed to ensure that Vincent conformed to professional rules of ethics. R&G also failed to conduct a proper conflict avoidance investigation in allowing Vincent to represent Insert, Calando II, and RXi in patent prosecution. R&G, when put on notice that Vincent's conduct did not meet applicable professional standards for representing an entity in CSHL's position in pursuing patents such as the Hannon Applications and did not conform to applicable rules of ethics also failed to notify CSHL of such facts.
- 117. R&G's failure to properly act in accordance with its duty of care, as described in Paragraphs 22-79 above, was grossly negligent.
- 118. In particular, by failing to properly manage and investigate Vincent, ensure that he conformed to professional rules of ethics, and timely notify CSHL about Vincent's conduct,

R&G's actions were grossly negligent and fell below the applicable professional standards for representing an entity in CSHL's position in pursuing patents such as the Hannon Applications.

- 119. Had R&G satisfied its duties of care to CSHL, R&G would have prevented or, at a minimum, ameliorated, the harm caused by the negligent and fraudulent acts as set forth in paragraphs 1-109 above and provided CSHL information to make an informed decision to seek substitute counsel.
- 120. As a direct and proximate result of R&G's negligence, CSHL has suffered damages in an amount to be determined at trial, including disgorgement of all attorneys' fees paid by CSHL to R&G since 2001, which is estimated to be no less than \$1,400,000, plus punitive damages.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, CSHL demands a trial by jury of all of its claims.

PRAYER FOR RELIEF

Wherefore, CSHL prays for judgment against R&G and Vincent as follows:

- a. Granting R&G and Vincent judgment on its Claims in a sum to be determined at trial, which is expected to be no less than \$37,500,000 to \$82,500,000 plus punitive damages;
- b. Awarding CSHL attorneys fees and costs; and
- c. Awarding CSHL such other and further relief as this Court deems just and proper.

COLD SPRING HARBOR LABORATORY,

By its attorney,

/s/ John O. Mirick

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Dated: August 10, 2011

CERTIFICATE OF SERVICE

I, John O. Mirick, hereby certify that this document(s), filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on August 10, 2011.

/s/John O. Mirick John O. Mirick, Esq.